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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,588	12/20/2001	Frederic Andre	SANSYL002	1696

7590 10/22/2003

Patent Department
Sanofi-Synthelabo Inc.
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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 10/22/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,588	ANDRE ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-9 and 11-34 is/are pending in the application.
- 4a) Of the above claim(s) 24, 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-9,11-23 and 25-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time and response to election requirement mailed 03/26/03.

Election Requirement

Applicants elected with traverse zwitterionic surfactant, alfuzosin active agent and a matrix that is free of active agent and corresponding claims 1-4, 6-9, 11-23 and 25-33. The traversal is on the grounds that the different species are "simply different embodiments of the single invention concept." However, the requirement was for applicants to elect specific composition for prosecution and upon the allowance a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141.

Examination is also extended to diltiazem as active agent.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 17, the term "other" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "other"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3, 7, 9, and 11-15 rejected under 35 U.S.C. 102(b) as being anticipated by Heinicke et al. (US 5,834,024).

Heinicke discloses a diltiazem tablet formulation comprising a core that is a sphere, bead or seed of an inert ingredient and the core comprises a pharmaceutical (diltiazem), a binder, emulsifier or stabilizer and the core may further include a dispersing agent, glidant and/or surfactant (column 4, lines 27-49). In example 1, the core is made up of diltiazem, hydroxypropylcellulose and sugar spheres, the core coated with EUDRAGIT RL AND EUDRAGIT RS. Regarding the delayed nature of the instant formulation as recited in claim 1, the formulation of the prior art would also be a delayed release composition since the prior art teaches the same polymers and would thus inherently produce a timed pulse release of the active agent. The presence of the hydroxypropylcellulose separates diltiazem from the polymer coating layer. The teachings of Heinicke meet the limitations of the claims.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-4, 6-9, 11-23 and 25-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andrieu et al. (US 5,589,190) in view of Wilson et al. (US 6,403,597).

Andrieu discloses pharmaceutical composition comprising alfuzosin hydrochloride core that is coated methacrylic acid copolymer (EUDRAGIT) (abstract). The formulation comprises tablets that afford immediate or sustained release or microparticles that provide immediate release of alfuzosin (columns 1-3 and claims 1-10).

Andrieu fails to teach the presence of surfactant in the alfuzosin formulation. However, Wilson teaches a formulation that comprises alfuzosin and surfactant (abstract, column 5, lines 39-44, column 6, 1-5 and column 12, line 40). Wilson is thus relied upon for the teaching that alfuzosin formulations can have surfactants. There is no demonstration in applicants' specification that the specific recited surfactants provide unusual results; and one surfactant may be substituted for another surfactant without affecting novel characteristic of the invention. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare alfuzosin formulation as disclosed by Andrieu. One having ordinary skill in the art would have been motivated to incorporate surfactant in the alfuzosin formulation with the expectation that the presence of the surfactant would facilitate the dissolution of alfuzosin.

Observation:

"Compromising" should be ---comprising---

Why is "stepped" enclosed in quotes

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5. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
Patent Examiner
Tech. Center 1600

